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EXAMINER

CAMPBELL, VICTORIA P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,468	Applicant(s) MOLINA ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-25, 27 and 29-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-25, 27 and 29-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II as defined by the examiner in the reply filed on November 26, 2008 is acknowledged. The traversal is on the ground(s) that the claims of the restriction have already been the subject of a search, examination, and a previous office action. This is not found persuasive because the claims as currently written comprise scopes differing from any of the claims originally examined in the case. The requirement is still deemed proper, however, the examiner has decided to withdraw the restriction requirement above and continue examination of all current claims.

Drawings

2. The drawings were received on July 29, 2008. These drawings are not accepted—see below.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the coating on the inner surface of the tubing as in claim 46 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claim is generally difficult to understand and applicant should consider revising to avoid confusion. Further, the final line of the claim is indefinite. The examiner has interpreted this limitation to mean "wherein the at least one layer of COPE material further comprises the at least one third layer".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 32, 1, 5, 8, 10, 11, 33, 34, 43-46, 38, 39, 21, 24, 25, 27, and 29-31 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/064909 A1 to Donohue et al.

Regarding claims 32, 1, 5, 8, 10, 11, 33, 34, and 43-46, Donohue et al disclose a tubing (1) for conveying fluidic media comprising at least one layer of COPE (Paragraph [0016]) where the at least one layer of COPE comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing (examiner notes that "inner peripheral surface" has been interpreted to refer to the inner surface of the COPE tubing). Further, Donohue et al disclose an inner layer having an open internal passage (3) and an intermediate layer for bonding the outer layer to the inner layer (2), wherein the intermediate layer comprises EVA (Paragraph [0020]) and the inner layer is comprised of polyurethane (Paragraph [0019]), wherein the outer and intermediate layers are free of PVC (Paragraph [0008]). COPE itself is a barrier to carbon dioxide, thus Donohue et al also disclose that the outer layer (of COPE) is a barrier to carbon dioxide. Further, the tubing comprises no more than one layer of COPE material (1), consists essentially of

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no more than one layer of COPE material (1), is free from other layers other than the at least one layer of COPE (1), the at least one layer of COPE is substantially free of other materials (1), and the inner surface is coated with a material for enhancing fluidic compatibility with the media (COPE).

Regarding claims 38, 39, 21, 24, 25, 27, and 29-31, Donohue et al disclose a process of making a tubing comprising selecting a COPE material and forming a tube (Paragraph [0021]) having at least one layer of COPE (1), wherein the COPE material comprises an outer peripheral surface and an inner peripheral surface of the tubing (see above). Further, Donohue et al disclose forming no more than one layer of the COPE (1), forming an inner layer (3), and forming an intermediate layer (2). Donohue et al further disclose that the outer layer is extruded COPE (1), the intermediate layer is extruded EVA (2), and that the layers can be singularly or co-extruded (Paragraph [0021]) and that the tubing is free from PVC (Paragraph [0008]) and the outer layer is a barrier to carbon dioxide (1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 6, 9, 35-37, 40-42, 22, 23, 2-4, and 7, as understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al.

Regarding claims 6, 9, and 35-37, Donohue et al discloses all the limitations of claim 1 as disclosed above, as well as a second layer for bonding (2) between an inner layer (3) and a third layer comprised of COPE (1). However, Donohue et al do not explicitly teach that the inner layer is comprised of COPE. At the time of the invention, one having ordinary skill in the art of medical tubing would have recognized that COPE is a useful material in making medical grade tubing without the use of harmful

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plasticizers (Paragraph [0016]) and would therefore find it obvious to make any and all layers of a medical tubing out of COPE. Donohue et al further disclose that the intermediate layer is comprised of EVA (2). Donohue et al also fail to explicitly teach or disclose the use of a plurality of layers of COPE material or that EVA is used between each set of adjacent layers of COPE. However, the examiner notes that the use of multiple layers of COPE tubing interspaced with EVA is simply a duplication of parts already disclosed by Donohue et al (layers 1 and 2) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 40-42, Donohue et al disclose all the limitations of claim 38 as disclosed above, but fail to teach or disclose the extrusion of a plurality of layers of COPE material or that EVA is extruded between each set of adjacent layers of COPE. However, the examiner notes that the extrusion of multiple layers of COPE tubing interspaced with EVA is simply a duplication of parts within a process already disclosed by Donohue et al (layers 1 and 2; Paragraph [0021]) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 22 and 23, Donohue et al teach all of the limitations of claim 21 as disclosed above, but fail to teach or disclose that the inner layer is comprised of an extruded layer of COPE. At the time of the invention, one having ordinary skill in the art

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of medical tubing would have recognized that COPE is a useful material in making medical grade tubing without the use of harmful plasticizers (Paragraph [0016]) and would therefore find it obvious to make any and all layers of a medical tubing out of COPE. Donohue et al further disclose that the outer layer is comprised of COPE (1).

Regarding claims 2-4 and 7, Donohue teach a tubing for conveying a fluidic media comprising an inner layer compatible with the media (3) and at least one layer of COPE material including an outer layer of COPE defining an outer peripheral surface of the tube, wherein the inner layer comprises polyethylene or polyurethane (Paragraph [0017]), specifically a high density polyethylene (Paragraph [0018]), as well as an intermediate bonding layer comprised of EVA (2). However, Donohue et al fail to explicitly teach or disclose the use of a plurality of layers of COPE material. However, the examiner notes that the use of multiple layers of COPE tubing is simply a duplication of parts already disclosed by Donohue et al (layer 1) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

12. Claims 12-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al in view of USPN 6,248,093 B1 to Moberg.

Regarding the above claims, Donohue et al disclose the device of claim 6 as described above, but fail to teach or disclose its use in a system. Moberg teaches a drug delivery system (Fig. 1) combining a pump (101, 102, 103, 104), reservoir (105), and tubing (106) for the delivery of insulin (Col. 1, lines 14-16). Further, Donohue et al

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disclose that the material of the second layer of tubing is EVA (2), that each of the second and third layers is comprised of a single layer (Fig. 1), that the intermediate and outer layers are free of PVC (Paragraph [0008]) and that the outer layer is a barrier to carbon dioxide (1). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use the tubing of Donohue et al in the medical system of Moberg because the tubing of Donohue et al does not contain plasticizers, which Donohue notes in Paragraph [0003] is detrimental to the delivery of insulin, such as that being delivered by the device of Moberg. Therefore, it would have been obvious to combine Donohue et al with Moberg to obtain the invention in the instant claims.

Response to Arguments

13. Applicant's arguments filed July 29, 2008 have been fully considered but they are not persuasive.

14. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the inner surface of the tubing must be the innermost surface of the tubing, for example, the surface which contacts the fluid) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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15. Regarding applicant's argument that Donohue et al do not suggest the use of COPE as the material to use for the inner layer, the examiner respectfully disagrees and draws applicant's attention to the argument above for further explanation.

16. Applicant's arguments with respect to claims 35-37 and 40-42 have been considered but are moot in view of the new ground(s) of rejection.

17. Regarding applicant's argument that Donohue et al only disclose multiple layer tubings, the examiner notes that the tubing of claim 38, and thus of claims 43 and 44, as defined by the examiner, simply refers to the outer layer (1) of Donohue et al, and further notes that this outer layer as defined by Donohue et al is free of other layers and comprises no more than one layer of COPE.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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